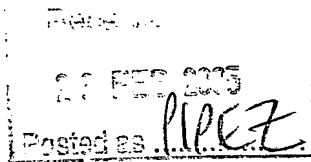


# PATENT COOPERATION TREATY

From the:  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
  
Baldwins  
PO Box 852  
Wellington 6001  
NEW ZEALAND



## PCT NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
day/month/year      17 FEB 2005

Applicant's or agent's file reference  
GL217658-142

### IMPORTANT NOTIFICATION

International Application No.  
**PCT/NZ2003/000222**

International Filing Date  
3 October 2003

Priority Date  
4 October 2002

Applicant  
A2 CORPORATION LIMITED et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>GL217658-142</b>	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No.  <b>PCT/NZ2003/000222</b>	International Filing Date (day/month/year)  3 October 2003	Priority Date (day/month/year)  4 October 2002
International Patent Classification (IPC) or national classification and IPC  <b>Int. Cl. <sup>7</sup> A61K 38/17, A61P 9/10</b>		
Applicant  <b>A2 CORPORATION LIMITED et al</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- |      |                                     |   |
|------|-------------------------------------|---|
| I    | <input checked="" type="checkbox"/> | Basis of the report   |
| II   | <input checked="" type="checkbox"/> | Priority  |
| III  | <input type="checkbox"/>            | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| IV   | <input type="checkbox"/>            | Lack of unity of invention  |
| V    | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI   | <input type="checkbox"/>            | Certain documents cited   |
| VII  | <input type="checkbox"/>            | Certain defects in the international application  |
| VIII | <input type="checkbox"/>            | Certain observations on the international application   |

Date of submission of the demand <b>4 May 2004</b>	Date of completion of the report <b>1 February 2005</b>
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer   <b>ARATI SARDANA</b> Telephone No. (02) 6283 2627

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**II. Priority**

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1).

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**The priority document for the present application could not be obtained. This opinion has been based on the assumption that the claimed subject matter of the present application validly derives its priority claim. If the present application is found to not validly claim its priority, then the disclosure of D3 would be of particular relevance.**

D3 discloses that  $\beta$ -casein A2 variant has atheroprotective effect, where as  $\beta$ -casein A1 variant is atherogenic. D3 also discloses that  $\beta$ -casein A2 lowers serum cholesterol. D3 is further directed to a diet containing  $\beta$ -casein A2 variant.

The above disclosure of D3 deprives claims 1-13 and 15 of their novelty and claims 14 and 16 of their inventive step.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	None	YES
	Claims	1-16	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-16	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)****CITATIONS:****D1: WO 01/00047 A****D2: Beales P. E. et al. "A multi-centre, blinded international trial of the effect of A1 and A2 B-casein variants on diabetes incidence in two rodent models of spontaneous Type I diabetes' Diabetologia, Vol. 45, No. 9, (September 2002), pg. 1240-1246****D3: Tailford Kristy A. et al. "A casein variant in cow's milk is atherogenic" Atherosclerosis, Vol. 170, No. 1, (September 2003) pg. 13-19****D4: McLachlan C. N. S. "B-casein A1, ischemic heart disease mortality, and other illnesses" Medical Hypotheses, Vol. 56, No. 2, (February 2001), pg. 262-272.****D5: Jim Mann and Murray Skeaff " Beta -casein variants and atherosclerosis -claims are premature" Atherosclerosis, Vol 170, No.1, (September 2003), pg. 11-12**

Documents D3 and D5 were published after the priority of the present application and before the international filing date therefore do not constitute prior art for the purpose of article 33(2) and 33(3) of the PCT. See however indications in Box II.

D5 discloses that, claims that, B-casein A1 causes cardiovascular disease and B-casein A2 is cardioprotective are not based on evidence and are speculative. The disclosure of D5 does not deprive claims 1-16 of their novelty or inventive step.

D4 discloses that milk protein B-casein A1 consumption correlates with ischaemic heart disease and diabetes. The disclosure of D4 does not deprive claims 1-16 of their novelty or inventive step.

**EXPLANATION:****Novelty (N) claims 1-16**

**D1** discloses dietary supplement containing type A2 beta-casein fraction for reducing the incidence of vascular disease including atherosclerosis in the population. This disclosure deprives claims 1-16 of their novelty.

**Continued in supplemental Box I**

**Supplemental Box I**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of BOX V**

D2 discloses dietary supplement having B-casein A2 added to it where B-casein is comprised of at least 95% of B-casein A2.

The above disclosure of D2 deprives claim 14 of its novelty.

**INVENTIVE STEP (IS) claims 1-16**

Claims 1-16 as for novelty.